REMARKS

Claims 1-5, 8, 9, 11-13, 15-17, 20-25, 27, 29, 37, 40, 41, 43, 44 and 46-48 are rejected under 35 U.S.C. §103 from Aoyama U.S. Patent No. 6,827,963 in view of Wester U.S. Patent No. 6,589,588, C.F.R. §101.83 and St.-Onge *et al.* "Consumption of a Functional Oil Rich in Phytosterols and Medium-Chain Triglyceride Oil Improves Plasma Profiles in Men," taken together, as further evidenced by Bailey pages 192-196 and 210-212.

The present amendment revises the single independent composition claim, single method-for-making independent claim 37, and single independent method-for-using claim 40. Each such claim continues to specify that the oil compositions are liquid vegetable oil compositions in which the interesterified liquid structured lipid component is a reaction product of between about 30 and 60 weight percent medium chain vegetable triglyceride and between about 40 and 70 weight percent long chain domestic vegetable oil triglyceride; that said medium chain triglyceride is selected from the group consisting of caprylic triglyceride, capric triglyceride, and combinations thereof; and that the domestic oil is selected from the group consisting of soybean oil, corn oil, cottonseed oil, canola oil, olive oil, peanut oil, safflower oil, sunflower oil, oil from grain plants, and combinations thereof. In addition, each independent claim more specifically defines the structured lipid component and interesterification in terms a randomization by which fatty acid chains are interchanged such that the fatty acid chains vary randomly from glycerol structure to glycerol structure.

Each such claim now also specifies that the interesterified liquid lipid component of the compositions is a structured lipid component having first fatty acid chains from medium chain vegetable triglyceride randomly interexchanged with second fatty acid chains from long chain domestic vegetable oil triglycerides, which first and second fatty acid moieties or chains vary randomly from glycerol structure to glycerol structure. Support is found in paragraphs [0009] and [0029] and elsewhere in the originally filed application.

Applicants have added the randomized structured lipid product features noted in the preceding paragraph. Aoyama fails to teach any such randomized interesterified product. With the present paper, it is clear claim 1 is not a product-by-process claim only but also the claimed product thus claimed is novel and patentable apart from the randomization interesterification called for in the claims. This claimed product has the first and second fatty acid chains on the glycerol structure and that vary from glycerol structure to glycerol structure.

More specifically, Aoyama teaches triglycerides in which specified fatty acids are combined so as to provide a specific acyl group at the first portion, a specific acyl group at the second portion and a specific acyl group at a third portion of the triglyceride molecule. This precise combination of precisely placed acyl groups is specifically taught as having specific triglyceride structures, disclosed by Aoyama as Formula I, Formula II, Formula II', Formula III, Formula III', Formula IV, Formula V or Formula VI.

Whether or not additional formulas might have been contemplated by Aoyama, Aoyama clearly does not disclose, teach or contemplate randomization interesterification or a triglyceride that is a randomization reaction product having

interchanged first and second fatty acid chains or moieties that vary randomly from glycerol structure to glycerol structure. Each specific acyl group must be in its proper place on the glycerol structure according to Aoyama's teaching.

Aoyama teaches glycerol backbones having specific acyl groups placed thereon at respective specific positions on the glycerol backbone, which would not have obviously led one of ordinary skill in the art to randomization interesterification of applicants' claimed compositions and methods. Nor would Aoyama have led one of ordinary skill to the randomized structured lipid component having first and second fatty acid chains or moieties that vary randomly from glycerol structure to glycerol structure.

Aoyama does not teach randomized triglycerides or randomization. Instead, Aoyama teaches the non-randomized triglycerides according to the designated Formulas mentioned above irrespective of the method by which they are made, whether following specific method steps and whether or not Aoyama mentions reaction process components such as enzymes or catalysts. One of ordinary skill would have been taught that only the specific triglyceride formulas are to be considered.

In the Office Action, Wester is relied upon to address Aoyama's failure to disclose phytosterol esters. Wester is cited as teaching incorporation of phytosterol esters into specific foods including cooking oils to reduce serum cholesterol in the body by reducing the absorption of cholesterol from the digestive tract. Wester has no teaching concerning random interesterification or the structured lipid components that are claimed by applicants and that are not taught or contemplated by Aoyama.

With respect to the CFR reference that the Office relies upon for showing levels of phytosterol ester fortification required to make labeling claims with regard to lowering

cholesterol and reducing coronary heart disease risk, this reference has no teaching concerning randomization interesterification or with applicants' claimed liquid structured lipid component having the randomly positioned first and second fatty acid chains or moieties. The St.-Onge reference is cited for its teaching of oils rich in phytosterols and medium chain triglyceride oil are known to improve plasma lipid profiles. St.-Onge does not remove Aoyama's or Wester's or the C.F.R.'s deficiencies regarding the claimed randomized interesterified structured lipids or the randomization interesterification that applicants claim. Similarly, Bailey is relied upon by the Office with respect to properties of viscosity and smoke point and melting points of certain vegetable oils, not randomization interesterification products or methods.

For these reasons, with the combination of references posited by the Office in this Office Action – even if they had been obvious to combine – one of ordinary skill would not have arrived at applicants' claimed invention. Reconsideration and withdrawal of the §103 rejection are respectfully requested with respect to claims 1, 37 and 40 and to their respective dependent claims.

To the extent the Office nevertheless continues to insist that it has made out a *prima facie* case of obviousness and in the event the Office still is not convinced that the claims as presently drafted are not obviously arrived at from this newly presented combination of five references, applicants respectfully remind the Office of the data already of record in this application as follows.

Applicants' claimed invention achieves an enhanced unexpected benefit when one compares the St.-Onge clinical study data with clinical testing using applicants' invention. Data in this St.-Onge article reports reduction in LDL cholesterol of 14%

when compared to the baseline. Data of the clinical study using applicants' claimed invention (2006 publication of Rudkowska et al. "Phytosterols Mixed with Medium-chain Triglycerides and High-oleic Canola Oil Decrease Plasma Lips in Overweight Men," which applicants filed in this application) show a reduction in LDL cholesterol of 21% when compared with the baseline.

More particularly, the respective clinical studies are properly compared due to similarities in testing protocol. The 2006 Rudkowska publication (applicants' claimed composition and methods) and the 2003 St. Onge publication each report on clinical testing of men having a body mass index of 25-31 kg/m^2. Twenty-three of these men completed the study using applicants' invention, while thirty men were in the study of the 2003 St.-Onge publication. Each study followed a randomized crossover type of test, and each delivered the phytosterol-containing component with the same isoenergetic meal protocol of 15% protein, 40% fat and 45% carbohydrates. In the 2006 clinical study according to applicants' claimed invention, blood samples were taken at days 1, 2, 41 and 42, whereas in the 2003 St.-Onge clinical study, blood samples were taken at days 1, 28 and 29. Each analyzed the blood samples and calculated LDL cholesterol using the Friedenwald formula.

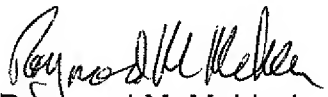
The baseline LDL for applicants' invention was 3.95, same being reduced to the end point value of 3.12, **a reduction of 21%**. *See* data in the table on page 393 in the "Functional Oil" columns and the "LDL-C" rows. As reported in Table 3 on page 1817 of the St.-Onge publication, the baseline for the functional oil (FctO) for LDL-C was 3.43, and the Endpoint was 2.96, **a reduction of 14%**. Thus, there is a 7% greater baseline

reduction with applicants' invention when compared with St.-Onge. This is an enhancement of half again the enhancement reported for St.-Onge.

Accordingly, these data provide further strong support for the unobviousness of the presently claimed invention. Reconsideration and withdrawal of the §103 rejection are further believed to be in order for this additional reason.

Applicants have made an earnest endeavor to place this application into condition for allowance, and favorable consideration is respectfully requested.

Respectfully submitted,



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